

DOCKET NO.: ALZA-0377 (ALZ5016USANP)
Application No.: 10/814,705
Office Action Dated: July 21, 2006

**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

Amendments to the Drawings

The attached drawing sheet includes amended Figure 5. The sheet containing amended Figure 5 replaces the sheet containing previous Figure 5.

Attachment: 1 replacement sheet containing amended Figure 5.

REMARKS

Following entry of the foregoing amendments, claims 1 to 16 will be pending in the application. Claim 1 has been amended herein. No new claims have been added, and no claims have been canceled. Figure 5 has been amended as discussed more fully below, and the specification has been amended to reflect the changes made to Figure 5. No new matter has been added.

Applicant respectfully requests reconsideration of the rejections of record in view of the foregoing amendments and the following remarks.

Objection to the Specification

New figure 5 submitted with the response filed May 10, 2006, and the amendments made to the specification in the response filed May 10, 2006, have been objected to under 35 U.S.C. § 132(a) as allegedly introducing new matter into the disclosure. Without conceding the correctness of the objection, Figure 5 has been amended to remove the second set of elements. In addition, in accordance with 37 C.F.R. § 1.83(a), the power source is shown as a rectangular box.¹ Support for the elements depicted in figure 5 that are not depicted in figure 4, i.e., the power source and the reservoir containing an active agent formulation, is found throughout the specification as originally filed, including, for example, lines 3 to 6 and 13 to 15 of paragraph 25, lines 1 to 4 of paragraph 30, lines 4 to 5 of paragraph 31, and figure 4. No new matter has been added.

In addition, paragraphs 26 and 33, and the new paragraph that was added to the specification in the response filed May 10, 2006 following paragraph 31, have been amended to reflect the changes made to figure 5. Support for the amendments is found throughout the specification as originally filed, including, for example lines 3 to 6 and 13 to 15 of paragraph 25, lines 1 to 4 of paragraph 30, lines 4 to 5 of paragraph 31, and figure 4. No new matter has been added.

The objections have thus been obviated, and Applicant respectfully requests withdrawal thereof.

¹ “conventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (*e.g.*, a labeled rectangular box). 37 C.F.R. § 1.83(a).

Alleged Lack of Written Description

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement because Applicant allegedly does not state in the specification that his electrotransport devices have a second reservoir, a second electrode, or an electrolyte formulation, except in originally filed claim 1. Applicant respectfully requests reconsideration and withdrawal of the rejection because original claim 1 provides adequate written description of the subject matter described in claim 1.

“There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976). However...the claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification ***and which is not conventional in the art or known to one of ordinary skill in the art.***” M.P.E.P. §2163 I.A. (emphasis added).

Adequate written description exists in the specification as originally filed for the subject matter of claim 1 because claim 1 is an original claim, and those skilled in the art would recognize that Applicant had possession of the subject matter of original claim 1 at the time the application was filed. Specifically, original claim 1 recites an electrotransport device comprising a second electrode and a second reservoir adapted to receive an electrolyte formulation. Since these features of electrotransport devices were conventional in the art at the time the application was filed, and since these features were thus known to those skilled in the art when the application was filed, recitation of the features in original claim 1 provides adequate written description of the features.

Although the Office states that “Applicant at no point mentions that their [*sic*] invention has a second reservoir, a second electrode, or an electrolyte formulation except in originally filed claim 1,”² as discussed above, these features of electrotransport devices were conventional in the art at the time the application was filed, and recitation of these features in original claim 1, therefore, provides adequate written description of the features. Nevertheless, the second reservoir, second electrode, and electrolyte formulation have been

² Office action dated July 21, 2006, page 4.

canceled from claim 1. Applicant accordingly, respectfully requests withdrawal of the rejection.

Alleged Anticipation

Claims 1 to 6 have been rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent Number 6,295,469 (“the Linkwitz patent”) because the patent allegedly discloses each limitation of claims 1 to 6. Applicant respectfully requests reconsideration and withdrawal of the rejection because the Linkwitz patent fails to describe or suggest numerous limitations of claims 1 to 6.

The Linkwitz patent fails to describe or suggest electrotransport devices that possess the features of the devices recited in present claims 1 to 6. For example, the electrotransport devices described in the Linkwitz patent do not have a non-conductive reservoir housing that has an internal cavity that contains *both* a first electrode and a first reservoir. As shown in figure 4 of the patent and described at column 10, lines 28 to 31, the donor electrode assembly **74** is comprised of a foam layer **81** having a centrally positioned cavity holding *only* a donor reservoir **82**. Notably, *the cavity does not contain an electrode*, but contains only donor reservoir **82**. Accordingly, the Linkwitz patent does not describe electrotransport devices comprising a reservoir housing having an internal cavity that contains both an electrode and a reservoir.

Although the Office asserts that the “centrally positioned cavity does in fact enclose and contain an electrode (see 72, 74; col 10, lns 28-34),” figure 4 illustrates a centrally positioned cavity containing *only* a reservoir, and no electrode is shown in the centrally positioned cavity in figure 4. Moreover, col 10, lns 28-34 of the Linkwitz patent state that the centrally positioned cavity holds *only* a donor reservoir:

As best shown in FIG. 4, the donor electrode assembly **74** is comprised of a foam layer **81** having a centrally positioned cavity holding a donor reservoir **82**, in which the compositions are held. Similarly, counter electrode assembly **73** is comprised of a foam layer **83** having a centrally positioned cavity holding a counter reservoir **83**. Preferably, reservoir **86** contains a solution of a biocompatible electrolyte.

In addition, the Linkwitz patent does not describe electrotransport devices comprising an electrically conductive element that is *integrally molded within* a non-conductive housing.

Rather, the Linkwitz patent describes electrotransport devices having a flexible connector **75** that connects electrode assemblies **73** and **74**,³ but, as shown in figure 4, flexible connector **75** is *not* integrally molded *within* a non-conductive housing. Instead, the lower surface of flexible connector **75** contacts the upper surfaces of foam layer **81** and donor reservoir **82**. Flexible connector **75** is thus *not integrally molded within* a housing. Notably, the Office concedes as much by stating that “the electrically conductive element is integrally molded *to* the non-conductive housing...”⁴ Moreover, although the Office asserts that “a portion of the electrically conductive element (72) does reside within and contact the centrally positioned cavity of the housing (72, 81, 82, 74; Fig 4),” figure 4, in fact, shows no such configuration. Figure 4 does not illustrate an electrically conductive element that is *within* the centrally positioned cavity of the housing. Rather, figure 4 illustrates a flexible connector **75** whose lower surface contacts the upper surface of foam layer **81** and donor reservoir **82**.

The Linkwitz patent thus fails to describe or suggest every limitation of the present claims, and Applicant accordingly, respectfully requests withdrawal of the rejection.

Alleged Obviousness

Claims 7 to 16 have been rejected under 35 U.S.C. § 103(a) as obvious over the Linkwitz patent because it would have allegedly been an obvious matter of design choice to modify the teachings of the Linkwitz patent to obtain the subject matter recited in claims 7 to 16. Applicants respectfully request reconsideration and withdrawal of the rejection because the Office has failed to establish *prima facie* obviousness.

To establish *prima facie* obviousness, the Patent Office must demonstrate that the cited prior art reference or combination of references teaches or suggests *all* the limitations of the claims. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

As discussed above in connection with the rejection for alleged anticipation, the Linkwitz patent fails to describe or suggest electrotransport devices that have a non-conductive reservoir housing that has an internal cavity that contains *both* a first electrode and a first reservoir. In addition, the Linkwitz patent fails to describe or suggest describe

³ Figure 5 and col. 9, lines 48 to 50.

⁴ Office action dated July 21, 2006, page 6 (emphasis added).

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electrotransport devices comprising an electrically conductive element that is *integrally molded within* a non-conductive housing. Since the Linkwitz patent fails to describe or suggest all the limitations of the cited claims, the Office has failed to establish *prima facie* obviousness. Applicant accordingly, respectfully requests withdrawal of the rejection.

Conclusion

Applicant submits that the foregoing constitutes a complete and full response to the Office action of record. Accordingly, an early and favorable action is respectfully requested.

Respectfully submitted,

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